

Attorney Docket: 26274  
Serial No.: 10/506,407

REMARKS

Upon entry of the forgoing amendments claims 31-35, 40-44, 67-69, 74-79 and 84 are pending in the application. Claims 36-39, 45-66, 70-73 and 80-83 have been withdrawn. Claim 31 have been amended. The amendments do not introduce any new subject matter within the meaning of 35 U.S.C. § 132. Therefore, entry of the amendments is respectfully requested.

**CLAIM OBJECTION**

The Examiner has objected to claim 31 because of a grammatical error. Applicants respectfully thank the Examiner for her comments and submit that amended claim 31 is now grammatically correct. Therefore, Applicants request that the Examiner reconsider and withdraw the object to claim 31.

**REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

Claims 31-35, 41-44, and 84 are rejected under 35 U.S.C. § 112, first paragraph as lacking a description in the specification of the step of "selecting a part or parts of the body in need of slimming effect," as recited in claim 31. In view of amended claim 31, Applicants respectfully submit that this rejection is moot.

As amended, claim 31 recites, "A method of cosmetic treatment for obtaining a slimming effect on the human body, comprising the application on the part or parts of the body presenting subcutaneous excess fat of an effective amount of a cosmetic composition containing an active agent selected from the group consisting of phytosphingosine and its cosmetically acceptable salts, to obtain a slimming effect." Support for amended claim 31 can be found in the present throughout the specification and at, for example, the abstract, paragraph 32, and the claims as originally filed. As the step of "selecting a part or parts..." is no longer recited, Applicant's respectfully request the Examiner withdraw the rejection of claims 31-35, 41-44, and 84.



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REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 67, 69, and 74-76 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson et al. (U.S. Patent No. 5,578,641), as applied to claims 31-32, 34 and 84, in view of U.S. Bombardeli et al. (U.S. Patent No. 5,679,358).

Also, claim 68 is rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Jackson et al., in view of Bombardelli et al., and in further view of Streekstra et al. (WO 00/53568).

Further, claim 77 has been rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Jackson et al., in view of Bombardelli et al., and in further view of Andre et al. (U.S. Patent No. 5,709,864).

Additionally, claims 67, 69, 74 and 78-79 are rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Jackson et al., in view of Andre et al.

Furthermore, claims 31-32, 34-35, 40-42 and 84 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson et al., in view of Bombardelli et al., as evidenced by Fiaschetti et al. (U.S. Patent No. 4,885,157)

Claim 33 is rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Jackson et al., in view of Bombardelli et al., and as evidenced by Fiaschetti et al., as applied to claims 31-32, 34-35, 40-42, and 84, in view of Streekstra et al.

Finally, claims 43-44 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson et al., in view of Bombardelli et al., and as evidenced by Fiaschetti et al., as applied to claims 31-32, 34-35, 40-42, and 84, in view of Streekstra et al., and in further view of Andre et al.

The U.S. Supreme Court in Graham v. John Deere Co., 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

A proper case of obviousness under 35 U.S.C. §103, requires that the prior art, as a whole, must suggest the desirability of making the claimed combination and provide a reasonable expectation of success. See *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988).

The *Dow* court further held that "In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered for the person of ordinary skill is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention." The court in *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994), held that "A prior art reference may be said to *teach away* when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." The court in *Busch & Lamb, Inc. v. Barnes-Hind/Hydro curve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986), held that "A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered."

Regarding motivation to modify a reference, the level of skill in the art cannot be relied upon to provide the suggestion to combine references. See *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308 (Fed. Cir. 1999). Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." *In re Mills*, 916 F.2d 680 at 682.

If a proposed modification would render the prior art invention being modified unsatisfactorily for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). In addition, if a proposed modification or combination of prior art references would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959).

Applicants respectfully traverse all of the instant rejections under 35 U.S.C. 103(a), because a *prima facie* case of obviousness has not been established.

**Jackson et al., in view of U.S. Bombardelli et al.**

The Examiner has rejected claims 67, 69, and 74-76 as being obvious over Jackson et al., in view of Bombardelli et al.

Applicants traverse this rejection.

Independent claim 67 of the present invention recites a cosmetic composition, notably intended for reducing subcutaneous excess fat, containing, as active agents: phytosphingosine or one of its cosmetically acceptable salts, and at least one lipolytic agent selected from the group consisting of CAMP and its cosmetically acceptable lipolytic derivatives, adenylate cyclase enzyme activating agents and phosphodiesterase enzyme inhibiting agents, in a cosmetically acceptable vehicle.

In contrast, Jackson et al. relates to cosmetic compositions having an anti-aging effect in that the compositions treat "dry, ageing or damaged skin to reduce moisture loss" by enabling stimulation of the synthesis of ceramides in the epidermis by the application of precursors of ceramides and/or by stimulation of the activity of enzymes responsible for catalyzing the steps in the biosynthetic pathway that yields ceramides. See, col. 13, lines 15-29. Phytosphingosine is taught by Jackson, et al. as a ceramide precursor.

Jackson et al. fail to teach or suggest a cosmetic composition for reducing subcutaneous excess fat. Further, as indicated by the Examiner, Jackson et al. fail to teach a composition containing phytosphingosine or one of its cosmetically acceptable salts, and at least one lipolytic agent.

Bombardelli, et al., the secondary reference, does not remedy the shortcomings of Jackson, et al. The teachings of Bombardelli, et al. are directed to the use of esculoside, a glucosidated coumarin extracted from the fruit pericarp and from the bark of *Aesculus hippocastanum*, alone or in combination with adenylate cyclase stimulators, such as forskolin or *Salvia miltiorrhiza* diterpenes and/or with phosphodiesterase inhibitors, such as apigenine-skeleton dimeric flavones, in topical formulations for the treatment of peripheral vasculopathies related to an impaired peripheral microcirculation, cellulitis or unesthetisms. Bombardelli et al. teach a composition useful in treatment of vascular related disorders that may improve early skin ageing. Bombardelli et al. do not teach a composition useful for reducing subcutaneous excess fat.

Furthermore, a person of ordinary skill in the art would not have motivation to combine the cited references.

Bombardelli et al. teach using esculoside alone or in combination with antiphosphodiesterase agents or adenylate cyclase stimulating agents can be used in chronic venous insufficiency, in Raynaud's disease and in acrocyanosis, as well as against cold-induced vasospasm. The higher blood flow to the areas treated with esculoside alone or esculoside in combination with antiphosphodiesterase agents or adenylate cyclase stimulating agents improve skin early ageing, particularly in the face and neck.

The Examiner asserts that one of ordinary skill in the art would combine the lipolytic agents of Bombardeli et al. with the composition of Jackson et al. In support of this, the Examiner cites *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980). However, according to *In re Kerkhoven*, "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition..." when they have "...been individually taught in the prior art." Contrary to the Examiner's assertion, Bombardeli et al. teach using esculoside either alone, or in combination with, adenylate cyclase stimulators, such as forskolin or *Salvia miltiorrhiza* diterpenes and/or with phosphodiesterase inhibitors, such as apigenine-skeleton dimeric flavones, in topical formulations for the treatment of peripheral vasculopathies related to an impaired peripheral microcirculation, cellulitis or unesthetisms.



Bombardelli et al. teaches that esculoside is useful in the treatment of different disorders due to venous deficiencies, such as cellulitis or for fighting against deposits of superfluous fats and that it could be combined with different lipolytic agents such as adenylate cyclase activating agents.

Those skilled in the art would not have been motivated to combine the compositions of Jackson et al. with the lipolytic agents of Bombardelli et al. because Jackson et al is not directed to an anti-ageing cosmetic treatment. The disclosure of Jackson et al. has nothing to do with the treatment of cellulitis disclosed in Bombardelli et al.

In view of the foregoing, it is submitted that nothing in Jackson et al. and Bombardelli et al., taken alone or together, renders the claimed invention obvious within the meaning of 35 U.S.C. § 103(a). Applicants respectfully submit that a *prima facie* case for obviousness has not been established. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Jackson et al., in view of Bombardelli et al., and in further view of Streekstra et al.

The Examiner has rejected claim 68 is under 35 U.S.C. § 103(a) as being unpatentable over Jackson et al., in view of Bombardelli et al., and in further view of Streekstra et al.

Applicants traverse this rejection.

The teachings of Jackson et al. and Bombardelli et al. are discussed above.

Streekstra et al. fail to remedy the failures of the Jackson et al. and Bombardelli et al. Streekstra et al. teach sphingoid base derivatives, specifically salts of thereof, and their use in compositions for topical use, and particularly, for the treatment of undesirable and/or abnormal conditions associated with dry skin, inflammation and/or microbial activity. These may include eczema, psoriasis, atopic dermatitis, acne, dandruff, mouth and/or lip infections, mycoses, various other skin infectious diseases or vaginal infections, as well as, wounds, burns, and overall normalisation of skinflora. See page 4, lines 15-21.

Streekstra et al. are completely silent with respect to the instant subject matter, i.e., slimming treatments, and there is no reason that the parts of the body which are concerned with the treatments of the instant application and those taught in Streekstra et al. should be viewed as the same.

In view of the foregoing, it is submitted that nothing Jackson et al., Bombardelli et al., and Streekstra et al, taken alone or in combination, renders the claimed invention obvious within the meaning of 35 USC § 103(a). Applicants respectfully submit that a *prima facie* case for obviousness has not been established. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Jackson et al., in view of Bombardelli et al., and in further view of Andre et al.

Claim 77 has been rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Jackson et al., in view of Bombardelli

et al., and in further view of Andre et al.

The teachings of Jackson et al. and Bombardelli et al. are discussed above.

Andre, et al. fail to remedy the deficiencies Jackson et al. and Bombardelli et al. Andre, et al. teach a cosmetic or a pharmaceutical composition, in particular a dermatological composition. The composition is characterized in that it comprises a cosmetically or pharmaceutically, and in particular dermatologically, effective quantity of an extract of a plant of genus Tephrosia, in particular an extract of the species Tephrosia purpurea. According to the invention, it has been discovered that the extract of the plant of genus Tephrosia is useful in preparing a cosmetic, pharmaceutical, and in particular dermatological composition. The compositions are primarily directed to anti-aging applications.

In contrast, the present invention is directed to compositions containing phytosphingosine that have a slimming effect. Therefore, , it is submitted that nothing Jackson et al., Bombardelli et al., and Andre et al, taken alone or in combination, renders the claimed invention obvious within the meaning of 35 USC § 103(a).

As such, the claim 77 is clearly non-obvious in view of Jackson et al., Bombardelli et al., and Andre et al. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection to claim 77.

Jackson et al., in view of Andre et al.

Claims 67, 69, 74 and 78-79 are rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Jackson et al., in view of Andre et al.

Applicants traverse this rejection.

The teachings of Jackson et al. and Andre et al. are discussed above.

In addition to the reasons given above with regard to the previous discussed rejection, the present invention is not obvious considering Jackson et al. in view of Andre et al. because the person of ordinary skill in the art would have reasonably expected a combination of the anti-ageing composition of Jackson et al. with the anti-ageing composition of Andre et al. to be successful in obtaining a slimming effect.

As such, applicants respectfully submit that a *prima facie* case for obviousness has not been established. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Jackson et al., in view of Bombardelli et al., as evidenced by Fiaschetti et al.

Claims 31-32, 34-35, 40-42 and 84 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson et al., in view of Bombardelli et al., as evidenced by Fiaschetti et al.

Independent claim 31 now recites a method of cosmetic

treatment for obtaining a slimming effect on the human body, comprising the application on the part or parts of the body presenting subcutaneous excess fat of an effective amount of a cosmetic composition containing an active agent selected from the group consisting of phytosphingosine and its cosmetically acceptable salts, to obtain a slimming effect.

The teachings of Jackson et al. and Bombardelli et al. are discussed above.

Fiaschetti et al. fail to remedy the deficiencies of Jackson et al. and Bombardelli et al. Fiaschetti et al. teach a cosmetic composition which beautifies and moisturizes the skin of a human being. The composition may also have therapeutic effects on the human skin such as the removal of lines or wrinkles, dissolution of fat pockets, the removal of bags under the eyes, and the closing of pores or gaps in the skin to render a smooth uniform appearance. The composition is comprised of seven basic ingredients, which include: live yeast cells, selenium, carotene, RNA, DNA, water and albumen. These core ingredients generally make up from about 80% to 100% of the composition used in the treatment, and are the basis for the advantages realized thereby.

As discussed above, with regard to independent claim 67, Jackson et al. and Bombardelli et al. do not render the present invention obvious. With particular regard to independent claim 31, Jackson et al. and Bombardelli et al. fail to teach or suggest a method of cosmetic treatment for obtaining a slimming effect by the application of an effective amount of a cosmetic composition containing an active agent selected from the group consisting of

phytosphingosine and its cosmetically acceptable salts.

There is no motivation whatsoever to combine Jackson et al. with Bombardelli et al. in view of claim 31. While Jackson et al. discloses a composition containing phytosphingosine, as discussed it does not teach or suggest a slimming effect as required by independent claim 31. As discussed with regard to the rejection of claim 67 and those claims that depend therefrom, Bombardelli teaches the use of esculoside alone or in combination with with adenylate cyclase stimulators, such as forskolin or Salvia miltiorrhiza diterpenes and/or with phosphodiesterase inhibitors, such as apigenine-skeleton dimeric flavones, in topical formulations for the treatment of peripheral vasculopathies related to an impaired peripheral microcirculation, cellulitis or unesthetisms. Claim 31 does not recite esculoside, adenylate cyclase stimulators, or phosphodiesterase inhibitors. Further, Bombardelli et al. do not teach or suggest the use of phystosphingosine. Therefore, Applicants respectfully submit that a person of ordinary skill in the art would not be motivated to combine Bombardelli et al. with any reference in order to obtain the presently claimed invention.

Similarly, the combination of the mere disclosure of a topical composition which may have an effect on fatty pockets localized around the eyes, but that has no relation to a composition containing phytosphingosine or its cosmetically acceptable salts (i.e., the composition of the present invention) and another completely unrelated composition that contains phytosphingosine cannot render the presently claimed invention obvious.

Additionally, a person of ordinary skill in the art would not realize the slimming effect of phytosphingosine or its cosmetically acceptable salts solely because other compounds which have no relation to compounds containing phytosphingosine or its cosmetically acceptable salts may have a slimming effect. Clearly, there would be no expectation of success. Such a conclusion could only be obtained by "a *posteriori*" appreciation of the present invention based on knowledge of it.

As such, claims 31-32, 34-35, 40-42 and 84 are clearly nonobvious in view of Jackson et al., Bombardelli et al., and Fiaschetti et al. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection to claims 31-32, 34-35, 40-42 and 84.

**Jackson et al., in view of Bombardelli et al., as evidenced by Fiaschetti et al. and in further view of Streekstra et al.**

Claim 33 is rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Jackson et al., in view of Bombardelli et al., and as evidenced by Fiaschetti et al., as applied to claims 31-32, 34-35, 40-42, and 84, in view of Streekstra et al.

Applicants hereby traverse this rejection.

Jackson et al., Bombardelli et al., and Fiaschetti et al. with regard to independent claim 31 as well as independent claim 67. Clearly the combination of Jackson et al., Bombardelli et al., and Fiaschetti et al. does not render the claimed invention, and specifically independent claim 31, obvious. Therefore, as claim 33 depends from claim 31, it would follow that this combination does

not render dependent claim 33 obvious. A person of ordinary skill in the art would not realize the slimming effect of phytosphingosine or its cosmetically acceptable salts solely because other compounds which have no relation to compounds containing phytosphingosine or its cosmetically acceptable salts may have a slimming effect.

Regarding claim 33, Streekstra et al. fail to remedy the deficiencies of Jackson et al., Bombardelli et al., and Fiaschetti et al. More specifically, for the same reasons as given above in the discussion of the previous rejection, there would be no motivation to combine Streekstra et al. with the other cited references to render the presently claimed invention obvious. Moreover, there would be no reasonable expectation of success to modify the references to obtain the presently claimed invention.

As claim 33 is clearly non-obvious in view of Jackson et al., Bombardelli et al., Fiaschetti et al., and Streekstra et al., Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

Jackson et al., Bombardelli et al., Fiaschetti et al.,  
Streekstra et al., and Andre et al.

Claims 43-44 have been rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Jackson et al., in view of Bombardelli et al., and as evidenced by Fiaschetti et al., as applied to claims 31-32, 34-35, 40-42, and 84, in view of Streekstra et al., and in further view of Andre et al.

This rejection is hereby traversed.



Applicants submit that as claims 43-44 depend from claim 31, if claim 31 is not rendered obvious, than claim 43-44 are also not rendered obvious.

As such, applicants respectfully submit that a *prima facie* case for obviousness has not been established. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**Regarding All Present Rejections under 35 U.S.C § 103(a)**

Finally, it is the Applicant's position that the Examiner's assertions with regard to all of the aforementioned rejections are the result of an "*a posteriori*" appreciation of inventive subject matter disclosed with knowledge of the present application.

**CONCLUSION**

In view of the foregoing, Applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement, and to examine all of the claims pending in this application.

If the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

Respectfully submitted,

**NATH & ASSOCIATES**

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